EXHIBIT A

CIVIL ACTION COVER SHEET

DOCKET NO.(S) 04-1255

Trial Court of Massachusetts
Superior Court Department
County: MIDDLESEX

PLAINTIFF(S)	DEFENDANT(S)
See List of Plaintiffs Attached	See List of Defendants Attached
ATTORNEY, FIRM NAME, ADDRESS AND TELEPHONE See List of Attorneys Attached Board of Bar Overseers number:	ATTORNEY (if known)

Origin code and track designation

Place an x in one box only:

- [X] 1. F01 Original Complaint
- [ ] 2. F02 Removal to Sup.Ct. C.231,s.104 (Before trial) (F)
- [ ] 3. F03 Retransfer to Sup.Ct. C.231,s.102C (X)
- [ ] 4. F04 District Court Appeal c.231, s. 97 &104 (After trial) (X)
- [ ] 5. F05 Reactivated after rescript; relief from judgment/Order (Mass.R.Civ.P. 60) (X)
- [ ] 6. E10 Summary Process Appeal (X)

TYPE OF ACTION AND TRACK DESIGNATION (See reverse side)

CODE NO.	TYPE OF ACTION (specify)	TRACK	IS THIS A JURY CASE?
B05	Product Liability	(A)	(X) Yes ( ) No

The following is a full, itemized and detailed statement of the facts on which plaintiff relies to determine money damages. For this form, disregard double or treble damage claims; indicate single damages only.

TORT CLAIMS
(Attach additional sheets as necessary)

A. Documented medical expenses to date: ** Expenses Listed Are Per Plaintiff **
1. Total hospital expenses - to date approximately ... $ 10,000.00
2. Total Doctor expenses - see hospital expenses above ... $
3. Total chiropractic expenses ... $
4. Total physical therapy expenses ... $
5. Total other expenses (describe) ... $
Subtotal $ 10,000.00

B. Documented lost wages and compensation to date - not yet determined ... $
C. Documented property damages to date ... $
D. Reasonably anticipated future medical and hospital expenses - approximately ... $ 250,000.00
E. Reasonably anticipated lost wages ... $
F. Other documented items of damages (describe)
$ 250,000.00

G. Brief description of plaintiff's injury, including nature and extent of injury (describe)

Each plaintiff, as a result of his or her ingestion of the diet drug, Redux (dexfenfluramine), has suffered injuries including heart valve disease, heart valve regurgitation, and/or pulmonary hypertension.

$
TOTAL $ 260,000.00

RECEIVED
IN THE OFFICE OF THE CLERK OF THE COURTS
MIDDLESEX
MAR 30 2004
CLERK

CONTRACT CLAIMS
(Attach additional sheets as necessary)

Provide a detailed description of claim(s):

TOTAL $.....

PLEASE IDENTIFY, BY CASE NUMBER, NAME AND COUNTY, ANY RELATED ACTION PENDING IN THE SUPERIOR COURT DEPARTMENT

"I hereby certify that I have complied with the requirements of Rule 5 of the Supreme Judicial Court Uniform Rules on Dispute Resolution (SJC Rule 1:18) requiring that I provide my clients with information about court-connected dispute resolution services and discuss with them the advantages and disadvantages of the various methods."

Signature of Attorney of Record _____ DATE: 3/26/04

AOTC-6 mtc005-11/99
A.O.S.C. 1-2000

CIVIL ACTION COVER SHEET
INSTRUCTIONS

SELECT CATEGORY THAT BEST DESCRIBES YOUR CASE

	CONTRACT	
A01	Services, labor and materials	(F)
A02	Goods sold and delivered	(F)
A03	Commercial Paper	(F)
A08	Sale or lease of real estate	(F)
A12	Construction Dispute	(A)
A99	Other (Specify)	(F)
	TORT	
B03	Motor Vehicle negligence-personal injury/property damage	(F)
B04	Other negligence-personal injury/property damage	(F)
B05	Products Liability	(A)
B06	Malpractice-medical	(A)
B07	Malpractice-other(Specify)	(A)
B08	Wrongful death,G.L.c.229,s2A	(A)
B15	Defamation (Libel-Slander)	(A)
B19	Asbestos	(A)
B20	Personal Injury-Slip&Fall	(F)
B21	Environmental	(A)
B22	Employment Discrimination	(F)
B99	Other (Specify)	(F)

	REAL PROPERTY	
C01	Land taking (eminent domain)	(F)
C02	Zoning Appeal, G.L. c.40A	(F)
C03	Dispute concerning title	(F)
C04	Foreclosure of mortgage	(X)
C05	Condominium lien and charges	(X)
C99	Other (Specify)	(F)
	EQUITABLE REMEDIES	
D01	Specific performance of contract	(A)
D02	Reach and Apply	(F)
D06	Contribution or Indemnification	(F)
D07	Imposition of Trust	(A)
D08	Minority Stockholder's Suit	(A)
D10	Accounting	(A)
D12	Dissolution of Partnership	(F)
D13	Declaratory Judgment G.L.c.231A	(A)
D99	Other (Specify)	(F)

	MISCELLANEOUS	
E02	Appeal from administrative Agency G.L. c. 30A	(X)
E03	Action against Commonwealth Municipality, G.L. c.258	(A)
E05	All Arbitration	(X)
E07	c.112,s.12S (Mary Moe)	(X)
E08	Appointment of Receiver	(X)
E09	General contractor bond, G.L. c.149,s.29,29a	(A)
E11	Workman's Compensation	(X)
E14	Chapter 123A Petition-SDP	(X)
E15	Abuse Petition, G.L.c.209A	(X)
E16	Auto Surcharge Appeal	(X)
E17	Civil Rights Act, G.L.c.12,s.11H	(A)
E18	Foreign Discovery proceeding	(X)
E96	Prisoner Cases	(F)
E97	Prisoner Habeas Corpus	(X)
E99	Other (Specify)	(X)

TRANSFER YOUR SELECTION TO THE FACE SHEET.

EXAMPLE:

CODE NO.	TYPE OF ACTION (SPECIFY)	TRACK	IS THIS A JURY CASE?
B03	Motor Vehicle Negligence-Personal Injury	(F)	☒ Yes ☐ No

SUPERIOR COURT RULE 29

DUTY OF THE PLAINTIFF. The plaintiff or his/her counsel shall set forth, on the face sheet (or attach additional sheets as necessary), a statement specifying in full and itemized detail the facts upon which the plaintiff then relies as constituting money damages. A copy of such civil action cover sheet, including the statement as to the damages, shall be served on the defendant together with the complaint. If a statement of money damages, where appropriate is not filed, the Clerk-Magistrate shall transfer the action as provided in Rule 29(5)(C).

DUTY OF THE DEFENDANT. Should the defendant believe the statement of damages filed by the plaintiff in any respect inadequate, he or his counsel may file with the answer a statement specifying in reasonable detail the potential damages which may result should the plaintiff prevail. Such statement, if any, shall be served with the answer.

A CIVIL ACTION COVER SHEET MUST BE FILED WITH EACH COMPLAINT, BUFF COLOR PAPER.

FAILURE TO COMPLETE THIS COVER SHEET THOROUGHLY AND ACCURATELY MAY RESULT IN DISMISSAL OF THIS ACTION.

ATTACHMENT TO CIVIL ACTION COVER SHEET

List of Plaintiffs:	**List of Defendants:**
Patsy Crouch, Roy Smith, Rita Laubner, and Jane McGinnis	Indevus Pharmaceuticals, Inc., F/K/A Interneuron Pharmaceuticals, Inc.; Wyeth, Inc., F/K/A American Home Products Corporation; Wyeth Pharmaceuticals, Inc F/K/A Wyeth-Ayerst Pharmaceuticals, Inc., A Division Of American Home Products Corporation; Boehringer Ingelheim Pharmaceuticals, Inc.,
List of Attorneys (for Plaintiffs):	
Edward J. Barshak, (BBO No. 032040) Michael S. Appel, (BBO No. 543898) Sugarman, Rogers, Barshak & Cohen, P.C. 101 Merrimac Street, 9th Floor Boston, MA 02114 (617) 227-3030 Stuart V. Kusin Michael A. Lee Susman Godfrey L.L.P. 1000 Louisiana, Suite 5100 Houston, TX 77002	

COMMONWEALTH OF MASSACHUSETTS

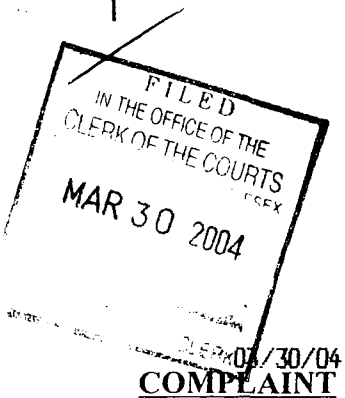
EASTERN COUNTIES, SS.SUPERIOR COURT

MIDDLESEX, SS.

04-1255

IN RE MASSACHUSETTS STATE COURT DIET DRUG LITIGATION

Civil Action No. _____



PATSY CROUCH, ROY SMITH, RITA LAUBNER, AND JANE MCGINNIS

Plaintiffs

v.

Indevus Pharmaceuticals, Inc., F/K/A Interneuron Pharmaceuticals, Inc.; Wyeth, Inc., F/K/A American Home Products Corporation; Wyeth Pharmaceuticals, Inc F/K/A Wyeth-Ayerst Pharmaceuticals, Inc., A Division Of American Home Products Corporation; and Boehringer Ingelheim Pharmaceuticals, Inc.,

Defendants

COMPLAINT

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40	240.00
CIVIL	960.00
SURCHARGE	15.00
SECC	20.00
041255 #	
SUBTTL	995.00
TOTAL	995.00
CHECK	995.00

Plaintiffs, as named herein (collectively referred to as "Plaintiffs"), by and through their undersigned counsel, sue Defendants, Indevus Pharmaceuticals, Inc., f/k/a Interneuron Pharmaceuticals, Inc.; Wyeth, Inc. f/k/a American Home Products Corporation; Wyeth Pharmaceuticals, Inc. f/k/a Wyeth-Ayerst Phamaceuticals, Inc., a Division of American Home Products Corporation; and Boehringer Ingelheim Pharmaceuticals, Inc. and upon information and belief, allege as follows:

Plaintiffs' Allegations

1. Plaintiffs file this action against the named Defendants for injuries, including but not limited to valvular heart disease ("VHD"), secondary pulmonary hypertension, and other associated

injuries suffered by Plaintiffs as a result of their ingestion of the defective and dangerous pharmaceutical diet drugs Redux™ and Pondimin® ("Diet Drugs") which were researched, created, formulated, tested, developed, designed, licensed, assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged and/or sold by Defendants, Indevus Pharmaceuticals, Inc., f/k/a Interneuron Pharmaceuticals, Inc. ("Interneuron" or "Defendant"); Wyeth, Inc. f/k/a American Home Products Corporation ("Wyeth Defendant" or "Defendant"); Wyeth Pharmaceuticals, Inc. f/k/a Wyeth-Ayerst Phamaceuticals, Inc. ("Wyeth Defendant" or "Defendant"); and Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer" or "Defendants") as more fully detailed herein below.

2. This action is brought on behalf of the following Plaintiffs:

a. Plaintiff Patsy Crouch is a citizen and resident of Lexington, KY suffering from VHD as a result of the ingestion, consumption and use of the Diet Drugs and is at risk of developing or is already suffering from secondary pulmonary hypertension and other related conditions as a direct and proximate result of said ingestion, consumption and use.

b. Plaintiff Roy Smith is a citizen and resident of Fairbanks, AK suffering from VHD as a result of the ingestion, consumption and use of the Diet Drugs and is at risk of developing or is already suffering from secondary pulmonary hypertension and other related conditions as a direct and proximate result of said ingestion, consumption and use.

c. Plaintiff Rita Laubner is a citizen and resident of Sutherland, NE suffering from VHD as a result of the ingestion, consumption and use of the Diet Drugs and is at risk of developing or is already suffering from secondary pulmonary hypertension and other related conditions as a direct and proximate result of said ingestion, consumption and use.

d. Plaintiff Jane McGinnis is a citizen and resident of Monticello, GA suffering from VHD as a result of the ingestion, consumption and use of the Diet Drugs and is at risk of developing or is already suffering from secondary pulmonary hypertension and other related conditions as a direct and proximate result of said ingestion, consumption and use.

3. Each and every Plaintiff was prescribed and did ingest dexfenfluramine, sold under the brand name Redux™. As well, upon information and belief, some of the Plaintiffs also ingested

fenfluramine, sold under both the generic name fenfluramine and the brand name Pondimin®, comprised of dexfenfluramine as its sole active ingredient.

4. Plaintiffs meet all medical criteria to qualify as intermediate and/or back-end opt-outs to the National Settlement. Specifically, Plaintiffs' echocardiograms, all of which were read and interpreted by board-certified cardiologists, demonstrate that they meet the definition of FDA positive heart valve regurgitation as defined by the National Settlement. Plaintiffs have properly exercised intermediate and/or back-end opt-out rights by completing, signing and timely submitting an opt-out form to the Settlement Court, the Trustees, and/or the Claims Administrator(s) and to the Wyeth Defendants. By filing this Complaint, Plaintiffs assert only those claims and is seeking only those damages as are permitted under the National Settlement. No other language in this Complaint shall be interpreted as Plaintiffs' intent to do otherwise. All aspects of this action are consistent with Plaintiffs' rights as an intermediate and/or back-end opt-out from the National Class Action Settlement.

5. Each and every Plaintiff named herein has filed this lawsuit within any applicable statute of limitations period.

6. Each and every Plaintiff named herein acted with diligence in attempting to discover any injury caused by their ingestion of the Diet Drugs, including following the advise of their physicians, monitoring their symptoms, and following the recommendations of the American Medical Association, American College of Cardiology, American Heart Association, American Society of Echocardiography, United States Department of Health and Human Services, and the National Diet Drug Settlement. Such Plaintiffs did not and could not have discovered their injury until they had an echocardiogram demonstrating the presence of FDA positive valvular heart disease, and could not have brought a cause of action against any of the named Defendants, including Defendant Interneuron until such Plaintiffs discovered that any injury detected was a result of the action and/or omissions of the named Defendants, including Defendant Interneuron.

7. Any statute of limitations period which applies to the Plaintiffs' claims against Defendant Interneuron, have been tolled under the principles of class action tolling as recognized by the Appeals Court of Massachusetts in DiCerbo v. Commissioner Of The Department Of Employment And Training, 54 Mass.App.Ct. 128, 763 N.E.2d 566 (Mass.App.Ct. 2003), citing American Pipe & Constr. Co. v. Utah, 414 U.S. 538, 554, 94 S.Ct. 756, 38 L.Ed.2d 713 (1974) and Crown, Cork & Seal Co. v. Parker, 462 U.S. 345, 353-354, 103 S.Ct. 2392, 76 L.Ed.2d 628 (1983), as multiple class actions against Interneuron have been filed in state and federal courts across the country, bringing claims which are substantially the same as those claims brought in this lawsuit, including the class action complaint, Doherty et al, v. Interneuron, et al, No. 98-0028-C, filed in Massachusetts state court in 1998 and which remained pending through the summer of 2001. Any effort by Defendant Wyeth to remove this case based on the principle of the fraudulent joinder of Defendant Interneuron is, therefore, an improvident removal, done solely to deprive Plaintiffs of their right to bring their claims in the forum of their choice.

Introduction

8. The Diet Drugs which Plaintiffs were prescribed and ingested, and which caused Plaintiffs to suffer valvular heart disease and associated injuries, were defective and unreasonably dangerous in that the Diet Drugs: were not reasonably safe for their intended use as a weight loss drugs; subjected Plaintiffs to risks which exceeded the benefits of the Diet Drugs, if any; were defective in design and formulation, making use of the drug more dangerous than an ordinary consumer would expect; were more dangerous than other risks associated with obesity and/or weight loss; and were otherwise defective and unreasonably dangerous as set forth herein.

9. The defective and unreasonably dangerous Diet Drugs caused Plaintiffs to suffer from valvular heart disease and resultant injuries and damages. Valvular heart disease ("VHD") is a serious and potentially fatal disease marked by the improper backward flow or "regurgitation" of blood within in the heart's chambers and blood vessels caused by the failure of the heart's valves, which separate the heart's chambers, from properly closing. When the heart's valves fail to close

sufficiently, a common result of Diet Drug ingestion, this causes the regurgitation of blood back into the chamber from which it has been pumped altering the hemodynamics within the heart. Such regurgitation is a progressive condition causing the heart to work harder to supply the body with adequate blood and oxygen. As the heart muscle is forced to over-work, physiological and morphological changes occur whereby the heart muscle becomes enlarged and distorted in shape. As a consequence, conditions and injuries suffered as a result of these and similar Diet Drug induced changes in the heart include but are not limited to: congestive heart failure, pulmonary hypertension, valve replacement surgery, and/or death.

10. Before the Plaintiffs were prescribed and ingested the Diet Drugs which caused them to suffer VHD and associated injuries, Defendants knew or should have known that the Diet Drugs had been related to and associated with these serious and life threatening side effects. The Defendants had an obligation under the law to disclose the association between their products and VHD.

11. Due to Defendants' failure to adequately warn the FDA and doctors prescribing the Diet Drugs of the known risks of VHD, Plaintiffs' physicians were unable to inform Plaintiffs of the true risks associated with the ingestion of the Diet Drugs including VHD. These side effects were known or should have been known to Defendants at the time that they marketed the drugs to the public based on, among other things, adverse event reports, clinical studies and the medical evidence of dangerous and potentially fatal side effects from the use of the drugs in Europe and elsewhere. Defendants did not, however, conduct adequate testing to establish the safety of the drugs before marketing them nor did Defendants perform adequate post-marketing surveillance and monitoring which would have otherwise prevented Plaintiffs' injuries. Rather, the Defendants through their marketing and promotional campaigns downplayed and/or obfuscated evidence of the serious and potentially fatal side effects that consumers of these drugs could face.

12. Defendant, Indevus Pharmaceuticals, Inc., f/k/a Interneuron Pharmaceuticals, Inc. ("Interneuron") has its principal place of business at the Ledgemont Center, 99 Hayden Avenue,

Lexington, Massachusetts and is incorporated in the State of Delaware. At all times relevant hereto, Interneuron was engaged in the business of researching, formulating, testing, developing, designing, licensing, assembling, compounding, marketing, promoting, distributing, detailing, and/or selling the pharmaceutical diet drug Redux. At all times relevant hereto, Interneuron researched, formulated, tested, developed, designed, licensed, assembled, compounded, marketed, promoted, distributed, detailed, and/or sold Redux through interstate commerce through the use of its employees and/or agents including Interneuron's field sales representative force or detailers who made direct contact with physicians including Plaintiffs' prescribing doctors. Beginning in or about 1989, Interneuron researched, created, formulated, tested, developed, designed, and/or licensed Redux. On or about November 19, 1992, Interneuron entered into a joint venture or partnership with American Cyanamid Company ("American Cyanamid" or "Wyeth Defendants"), a predecessor company to the Wyeth Defendants, and Les Laboratories Servier ("Servier") pursuant to the terms of a "Patent and Know-How Sublicense Supply Agreement" for the manufacturing, marketing, labeling, promotion and sale of Redux. On or about November 21, 1995, Defendant, Interneuron, entered into an exclusive "Contract Manufacturing Agreement" with Defendant, Boehringer, by which Boehringer agreed to manufacture, develop, test, assemble, package, label, prepare and/or supply Redux exclusively for and/or to Defendant, Interneuron, including supplying Defendant, Interneuron, with all of its requirements of Redux for ultimate sale in the United States including the State of Massachusetts. On or about June 1, 1996, Interneuron entered into a "Co-promotion Agreement" with the Wyeth Defendants which both reaffirmed the pre-existing joint venture or partnership between Interneuron and the Wyeth Defendants and provided for Interneuron to market, promote, advertise, distribute, label, detail, supply, package and/or sell Redux in consideration for the payments from Interneuron's co-promoter, Wyeth Defendants, for percentages of profit derived from sales generated by Interneuron's sales representative sales force. At all times material hereto, Interneuron does and did business in the State of Massachusetts and researched, created, formulated, tested, developed, designed, licensed, assembled, compounded, manufactured, marketed, promoted,

advertised, distributed, labeled, detailed, supplied, packaged and/or sold the pharmaceutical known as Redux in interstate commerce and in the various States within which Plaintiffs were prescribed and ingested the Diet Drugs.

13. The Defendant, Wyeth, Inc., f/k/a American Home Products Corporation, is a Delaware corporation with its principal place of business at 5 Giralda Farms, Madison, New Jersey. At all times material hereto, this Defendant manufactured, supplied, packaged, labeled, detailed promoted, advertised, marketed, distributed and/or sold the pharmaceuticals known as Pondimin and Redux. A.H. Robins Company, Incorporated ("A.H. Robins") was a corporation, organized and existing under the laws of the State of Delaware, which manufactured, supplied, packaged, labeled, detailed promoted, advertised, marketed, distributed and/or sold Pondimin for many years between 1973 and 1990. A.H. Robins had its principal place of business in the State of Virginia until at least 1990, when it was acquired by American Home Products Corporation, now known as Wyeth, which company has assumed all responsibility for any liability of A.H. Robins arising from its manufacturing, supplying, packaging, labeling, detailing, promoting, advertising, marketing, distributing and/or sale of Pondimin. On or about November 19, 1992, Wyeth, Inc., through another predecessor company, American Cyanamid, whose assets and liabilities it later acquired, entered into a joint venture or partnership with Interneuron Pharmaceuticals, Inc. and Servier pursuant to the terms of a "Patent and Know-How Sublicense Supply Agreement" for the manufacturing, supplying, packaging, labeling, detailing, promoting, advertising, marketing, distributing and/or sale of Redux and at all times material was engaged in a joint venture or partnership with Interneuron Pharmaceuticals, Inc., Servier, and Boehringer Ingelheim, Inc., in the manufacturing, supplying, packaging, labeling, detailing, promoting, advertising, marketing, distributing and/or sale of Redux. On or about June 1, 1996, this Defendant entered into a "Co-promotion Agreement" with Interneuron Pharmaceuticals, Inc. that reaffirmed the joint venture or partnership between this Defendant and Interneuron Pharmaceuticals, Inc. At all times material hereto, this Defendant does and did business in the State of Massachusetts and researched, created, formulated, tested,

developed, designed, licensed, assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged and/or sold the pharmaceutical known as Pondimin and Redux in interstate commerce and in the various States within which Plaintiffs were prescribed and ingested the Diet Drugs.

14. The Defendant, Wyeth Pharmaceuticals, f/k/a Wyeth-Ayerst Laboratories, Inc., is a Delaware Corporation with its principal place of business at 555 Lancaster Avenue, St. Davids, Pennsylvania. At all times material hereto, this Defendant manufactured, supplied, packaged, labeled, detailed promoted, advertised, marketed, distributed and/or sold the pharmaceuticals known as Pondimin and Redux. A.H. Robins was a corporation, organized and existing under the laws of the State of Delaware, which manufactured, supplied, packaged, labeled, detailed promoted, advertised, marketed, distributed and/or sold Pondimin for many years between 1973 and 1990. A.H. Robins had its principal place of business in the State of Virginia until at least 1990, when it was acquired by American Home Products Corporation, now known as Wyeth, which company has assumed all responsibility for any liability of A.H. Robins arising from its manufacturing, supplying, packaging, labeling, detailing, promoting, advertising, marketing, distributing and/or sale of Pondimin. On or about November 19, 1992, Wyeth, Inc., through another predecessor company, American Cyanamid, whose assets and liabilities it later acquired, entered into a joint venture or partnership with Interneuron Pharmaceuticals, Inc. and Servier pursuant to the terms of a "Patent and Know-How Sublicense Supply Agreement" for the manufacturing, supplying, packaging, labeling, detailing, promoting, advertising, marketing, distributing and/or sale of Redux and at all times material was engaged in a joint venture or partnership with Interneuron Pharmaceuticals, Inc., Servier, and Boehringer Ingelheim, Inc., in the manufacturing, supplying, packaging, labeling, detailing, promoting, advertising, marketing, distributing and/or sale of Redux. On or about June 1, 1996, this Defendant entered into a "Co-promotion Agreement" with Interneuron Pharmaceuticals, Inc. that reaffirmed the joint venture or partnership between this Defendant and Interneuron Pharmaceuticals, Inc. At all times material hereto, this Defendant does and did business

in the State of Massachusetts and researched, created, formulated, tested, developed, designed, licensed, assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged and/or sold the pharmaceutical known as Pondimin and Redux in interstate commerce and in the various States within which Plaintiffs were prescribed and ingested the Diet Drugs.

15. The Defendant, Boehringer Ingelheim Pharmaceuticals, Inc. ("Boehringer"), is a Delaware Corporation with its principal place of business at 900 Ridgebury Road, Ridgefield, Connecticut 06877. At all times material hereto, this Defendant was in the business of manufacturing, assembling, developing and/or supplying the pharmaceutical known as Redux. On or about November 21, 1995, Defendant, Boehringer, entered into an exclusive "Contract Manufacturing Agreement" with Defendant, Interneuron, by which Boehringer agreed to manufacture, develop, test, assemble, package, label, prepare and/or supply Redux exclusively for and/or to Defendants, Interneuron and Wyeth Defendants, including supplying Defendants Interneuron and the Wyeth Defendants, with all of its requirements of Redux for sale in the United States. At all times material hereto, Boehringer does and did business in Massachusetts and manufactured, developed, tested, assembled, packaged, labeled, prepared and/or supplied Redux in interstate commerce and in the various States within which Plaintiffs were prescribed and ingested the Diet Drugs. Upon information and belief, the Redux ingested by Plaintiffs was manufactured, developed, tested, assembled, packaged, labeled, prepare and/or supplied by Boehringer. Though "Diet Drugs" as provided herein shall otherwise include both Redux and Pondimin, all allegations referencing "Diet Drugs" as set forth herein relating to Boehringer shall only relate to Redux.

Factual Background.

16. Aminorex, discovered in 1960 by United States pharmaceutical company, McNeil Laboratories, was a drug from the same family of drugs as fenfluramine and dexfenfluramine. Aminorex was touted as a wonder weight loss drug which, like fenfluramine and dexfenfluramine, worked by increasing brain serotonin while inhibiting reuptake of serotonin.

17. Fenfluramine is made up of two "mirror image" halves or isomers: dexfenfluramine (right-handed isomer or d-isomer), the isomer which increases the release and prevents the reuptake of serotonin in the brain, thereby presumably reducing appetite, and levofenfluramine (left-handed isomer or l-isomer), which increases dopamine release but can cause the unwanted side-effect of drowsiness.

18. In 1963, Science Union & Co., an affiliate of Servier, entered into a licensing agreement with Wyeth Defendants' predecessor, A.H. Robins, giving it the right to market, promote, distribute, detail, sell or otherwise profit from the sale of fenfluramine in the United States.

19. In 1965, after securing authorization for the marketing of fenfluramine in Europe, Servier commenced the sale of products containing fenfluramine in Europe. This same year, Aminorex was introduced into the European market.

20. However, by 1967, evidence began to surface that the ingestion of Aminorex was associated with pulmonary hypertension. Over the next five years, Aminorex caused in Europe a ten-fold increase in pulmonary hypertension cases, permanent injury to patients who suffered significant oxygen deprivation, and numerous deaths. In light of the reports of Aminorex induced pulmonary hypertension, McNeil Laboratories prudently suspended its research and efforts to bring Aminorex to the United States market. By 1972, Aminorex was removed from the European market.

21. In or about 1970, during the European experience, Dr. Richard Wurtman, a faculty member of the Massachusetts Institute of Technology (MIT) and the founder of Interneuron secured a United States patent for use of fenfluramine as a diet drug. Like Aminorex, Fenfluramine was touted as a wonder weight loss drug designed to effect weight loss by increasing brain serotonin while inhibiting reuptake of serotonin. The patent and rights to market fenfluramine as an obesity drug were thereafter sub-licensed by Dr. Wurtman and/or MIT to Servier.

22. Despite the European experience, in June of 1973, fenfluramine was introduced into the United States market by A.H. Robins which sold fenfluramine under the brand name Pondimin. However, after introduction into the United States market, sales of fenfluramine languished both

because of restrictions in prescribing under the Controlled Substance Act and because the fenfluramine isomer levofenfluramine caused users to become lethargic and tired when using Pondimin alone.

23. In 1977, Finnish researchers found a causal link between fenfluramine/ dexfenfluramine and heart valve lesions. Based on a study of weight-loss drugs including Aminorex and fenfluramine/dexfenfluramine and their effects on the release of serotonin, it was discovered that not only was the concentration of free serotonin in the blood vessels of the lungs caused by the weight-loss drug responsible for pulmonary hypertension, but also that the vessel wall-thickening mechanism which caused pulmonary hypertension was likely the identical mechanism which caused right-sided heart valve thickening and regurgitation in carcinoid patients.

24. Recognizing the problems in selling fenfluramine caused by the levofenfluramine isomer which caused users to become lethargic and tired, in or about 1980, Servier discovered a commercially feasible way to chemically isolate and separate the active ingredient in fenfluramine, being the right-sided d-isomer (dexfenfluramine) from the undesirable left-sided isomer (levofenfluramine) and commissioned and/or contracted Dr. Wurtman and/or MIT to further research, formulate, test, develop, design, license, assemble, compound, manufacture, market, promote, advertise, distribute, label, detail, supply, package and/or sell Redux for the United States market. This same year, MIT and/or Dr. Wurtman, secured a United States patent for use of dexfenfluramine as an obesity drug and thereafter, as with fenfluramine a decade earlier, sub-licensed the patent back to Servier.

25. On October 3, 1981, Dr. J.G. Douglas published Pulmonary Hypertension and Fenfluramine in the British Medical Journal. On January 25, 1986 an article entitled Irreversible Pulmonary Hypertension after Treatment with Fenfluramine, was published in the British Medical Journal. Defendants knew, or should have known, of the British Medical Journal articles and how those articles related to fenfluramine and dexfenfluramine, and their propensity to cause valvular heart disease, and secondary pulmonary hypertension.

26. While the sales of Pondimin languished between 1973 and 1984, sales of Pondimin increased, however, after several studies or reports sponsored, subsidized, and/or supported by the Wyeth Defendants' predecessor, A.H. Robins, were published within the medical community. Specifically, in 1984, Dr. Michael Weintraub published A Double-Blind Clinical Trial in Weight Control: Use of Fenfluramine and Phentermine Alone and in Combination in the Archives of Internal Medicine. Dr. Weintraub's study was sponsored, subsidized, and/or supported by A.H. Robins (later acquired by the Wyeth Defendants). Despite noting some adverse effects associated with fenfluramine, Dr. Weintraub failed to examine the long-term safety of fenfluramine. Instead, the study focused on the short-term effectiveness of the drugs used individually, and in combination with phentermine.

27. In 1985, after securing authorization for the marketing of dexfenfluramine in Europe, Servier commenced the sale of products containing dexfenfluramine in Europe under the brand/trade names Adifax (in England) and Isomeride (in France).

28. In or about 1989, after MIT and Dr. Wurtman had researched, formulated, tested, developed, designed, licensed, assembled and compounded dexfenfluramine for several years in preparation for submitting dexfenfluramine for FDA approval and licensing for sale in the United States, Dr. Wurtman incorporated Defendant, Interneuron.

29. In or about 1990, Servier sub-licensed the rights to market, promote, distribute, detail, sell or otherwise profit from the sale of dexfenfluramine in the United States back to Interneuron.

30. On or about February 27, 1990, representatives from Interneuron, Wyeth Defendants and Servier convened to discuss "certain situations pertaining to Pondimin", including protocols and respective responsibilities relating to adverse event reporting and safety information, during which Servier representatives Madame Derome-Tremblay and Christine Bazantay advised the Wyeth Defendants that there was a need to update the 1972 labeling for Pondimin. However, there was no change in the labeling of Pondimin between 1990 and mid-1996.

31. In September of 1990, Servier, co-licensor of both Pondimin and Redux in coordination with Interneuron and the Wyeth Defendants, completed a study regarding the effects of fenfluramine isomers on Fisher Rats which showed significant levels of focal fibrosis in the hearts of rats treated with doses of dexfenfluramine as compared with hearts of untreated rats. Defendants knew or should have known of the Fisher Rat study and how those articles related to fenfluramine and dexfenfluramine. At the very least, Interneuron and the Wyeth Defendants knew or should have known of the results of the Fisher Rat study by March 19, 1992, the date that the study was released by Servier.

32. On March 18, 1991, Interneuron, filed a petition with the DEA requesting that fenfluramine and its isomer dexfenfluramine be removed from Schedule IV and all other controls of the Controlled Substances Act (CSA) such that, among other things, both Pondimin and Redux could be dispensed and prescribed in larger quantities and over longer incremental dosage durations. Interneuron's efforts to gain the de-scheduling of both fenfluramine and dexfenfluramine, continued by using politicians and large anti-regulatory political action committees aimed at persuading both the DEA and FDA.

33. On or about October 25, 1991, Interneuron, through the assistance of Cato Research, Ltd. filed an Investigational New Drug Application with the FDA in furtherance of securing approval for Redux.

34. In 1992, Dr. Weintraub again published a series of articles sponsored, subsidized, and/or supported by the Wyeth Defendants in Clinical Pharmacological Therapies, in which he reported his research regarding the long term use of fenfluramine and phentermine for weight control. Dr. Weintraub's research assumed the safety of fenfluramine, and did not examine the short-term or long-term safety of the drug. The Wyeth Defendants failed to conduct or fund any studies or research regarding the long-term safety of the fenfluramine. The Wyeth Defendants, and later Interneuron, through their sales representative force, promoted Dr. Weintraub's conclusion that long term combination use of fenfluramine and phentermine was effective for the management of

obesity to both physicians, and the public. As a result, sales of Pondimin began to increase dramatically.

35. On or about November 19, 1992, Interneuron entered into a joint venture or partnership with American Cyanamid, a predecessor company to the Wyeth Defendants, and Servier pursuant to the terms of a "Patent and Know-How Sublicense Supply Agreement" for the manufacturing, marketing, labeling, promotion and sale of Redux.

36. On or about April 15, 1993, Interneuron and Wyeth Defendants, through their employees, agents and/or representative parties, including Dr. Bobby W. Sandage, Jr., Interneuron's Vice-President of Research and Development and employees Dukart, Hammershaimb, Gantt, Lefkowitz, Stout and Quinn of Wyeth Defendants, met with Dr. Stuart Rich, Section of Cardiology at University of Illinois at Chicago, an expert in the area of pulmonary hypertension ("PH"), to discuss the cases of PH reported following the use of Redux and "to help put this information into perspective." Interneuron and Wyeth Defendants at this time recognized Dr. Rich as a Principal Investigator and member of the steering committee for the NIH Registry for the Characterization of PH who had reviewed approximately thirty-six (36) cases of the drug relationship between Redux and PH and further admitted that there was an association between PH and the intake of certain exogenous substances such as and including Redux. Dr. Rich advised Interneuron and Wyeth Defendants that there was an increased risk for PH which necessitated caution until more definitive information was available. This information placed or should have placed the Defendants on notice of the association between the Diet Drugs and pulmonary hypertension, and that pulmonary hypertension may be related to valvular heart disease.

37. By 1993, the Wyeth Defendants labeling for Pondimin indicated that there were only 4 reported cases of pulmonary hypertension reported in association with the drug. Yet, that same year, Dr. Francois Brenot published an article related to the association of Fenfluramine and pulmonary hypertension, in the British Heart Journal. Dr. Brenot identified 25 cases of pulmonary hypertension associated with the use of fenfluramine and/or dexfenfluramine. The Wyeth

Defendants knew or should have known of the Brenot article. The Wyeth Defendants should have known by at least 1993 that Pondimin was defective and unreasonably dangerous and further that its Pondimin labeling was false.

38. On or about May 21, 1993, Interneuron filed its NDA with the FDA for the approval of Redux. In its bid for FDA's Redux approval, Interneuron and Wyeth Defendants relied upon several pivotal "studies" in its NDA, including but not limited to, the Noble Study, the Van Itallie Study, and the Index Study.

39. Interneuron and Wyeth Defendants knew at the time of submitted the NDA for Redux to the FDA that these pivotal studies where flawed, defective and substandard, thereby effecting misrepresentations to the FDA, the medical community, Plaintiffs' prescribing physicians and Plaintiffs. In particular, Interneuron and Wyeth Defendants were on notice through advice by Interneuron's own auditor, Bruce Sturgeon (such internal audits being typically required and expected of NDA applicants), both before and during the NDA submission and subsequent supportive documentation, that:

a. The Noble Study had careless record keeping, several protocol violations, a lack of documentation for final disposition of the drug and missing progress reports to the IRB;

b. the Van Itallie Study, which Mr. Sturgeon concluded would probably not be accepted by the FDA – though Interneuron still included the same in its NDA — included a protocol change increasing the allowable weight fluctuation from 3 kilograms to 7.5 percent of body weight without notifying the IRB or FDA, thereby reflecting a gross deviation from good clinical practices; used three patients who did not meet the revised criteria for the study; and contained inaccurate drug accountability for all patients, exacerbated by the fact that the drug was a controlled substance; and

c. the Index Study was poorly monitored, lacked proper and complete documentation, contained high error incidents in key data reporting found across all sites, and suffered from poor data quality consistent among all sampled sites which could be extrapolated to all sites in the Index Study.

40. During the time Interneuron filed its NDA for Redux, Interneuron and Wyeth Defendants knew or should have known that there were serious health risks associated with Redux which were neither sufficiently nor adequately expressed in either its NDA or its 120 Day Update.

41. By 1993, nearly two decades after the 1977 Finnish study, numerous medical reports and studies had been published within mainstream medical journals and publications firmly establishing the same causal connection between high concentrations of free circulating serotonin, as caused by fenfluramine and dexfenfluramine, and heart valve lesions, including but not limited to: Ann Redfield MM, Nicholson WJ, Edwards WD, Tajik AJ. Valve disease associated with ergot alkaloid use: echocardiographic and pathologic correlations. Ann Intern Med 1992;117:50-52; and Pellikka PA, Tajik AJ, Khandheria BK, et al. Carcinoid heart disease: clinical and echocardiographic spectrum in 74 patients. Circulation 1993;87:1188-96. As reaffirmed by these medical journal publications and their long and numerous progeny spanning nearly three decades, there was an available body of scientific knowledge identifying the pharmacologic affects of various anorexic agents, including fenfluramine and dexfenfluramine, on circulating (release, reuptake inhibition and monoamine oxidase inhibition) serotonin. Moreover, there was an available body of scientific knowledge relating elevations in serotonin as found in ergotamine toxicity and carcinoid syndrome, like fenfluramine and dexfenfluramine, to incidents of VHD. During this period of time in which Interneuron and the Wyeth Defendants were proceeding with the Redux NDA and while the Wyeth Defendants continued to sell Pondimin on the United States market, Interneuron and Wyeth Defendants knew or should have known that fenfluramine and dexfenfluramine caused an increase in circulating serotonin and that a serotonin-related mechanism was directly associated with VHD. Interneuron and Wyeth Defendants failed to disclose the connection between the Diet Drugs and VHD and/or failed to perform pre-marketing studies and post-marketing surveillance which would have detected this fact.

42. In or about 1994, cases of heart valve damage from the use of the Diet Drugs began to appear throughout the Country including sonographer, Pamela Ruff's discovery in Fargo, North

Dakota of VHD in patients who had ingested Pondimin. Numerous cases of Diet Drug induced VHD prompted physicians at the Mayo Clinic to undertake a case review which ultimately resulted in the untimely forced withdrawal of the Diet Drugs from the market.

43. In February 1994, the preliminary results of the International Primary Pulmonary Hypertension study ("IPPH Study") entitled "Appetite Suppressants and the Risk of Primary Pulmonary Hypertension" was released and available to the Defendants. The preliminary results of the IPPH Study confirmed the association between fenfluramine and dexfenfluramine and pulmonary hypertension. The Defendants failed to reveal the number of cases of pulmonary hypertension associated with the Diet Drugs to the public, Plaintiffs, or Plaintiffs' prescribing physicians.

44. In March and April of 1994, Wyeth Defendants received 10 reports relating to VHD in the consumer public a result of the use of Pondimin, which indicated or should have indicated a clear signal to Wyeth and their partners including Interneuron of the association between the Diet Drugs and VHD.

45. On or about March 23, 1994, Dr. Sandage and Lisa Stockbridge of the FDA discussed the pending NDA for Redux, at which time Dr. Stockbridge and Dr. Sandage of Interneuron discussed the concerns about the pulmonary hypertension issue and that the concerns might have been strong enough to consider withdrawing the NDA.

46. On June 24, 1994, the Wyeth Defendants' Safety Surveillance Monitor, Amy Myers, wrote a memo to Wyeth Defendants' Medical Monitor, Fred Wilson, and indicated that the Wyeth Defendant's database contained 37 cases of pulmonary hypertension associated with Pondimin.

47. After a hostile bid to acquire American Cyanamid commenced in mid-1994, American Home Products Corporation completed its acquisition of American Cyanamid in November of 1994, acquiring its assets and liabilities, and securing its rights to the sublicense agreement between Interneuron, American Cyanamid and Servier.

48. By October 10, 1994, Wyeth Defendants, through its leadership, Hans Mueller and Fred Hassan, agreed to pay Interneuron $8 million dollars, representing American Cyanamid's equity investment in Interneuron and its dexfenfluramine licensing fees, to obtain Interneuron's approval for Wyeth Defendants having more direct participation in Redux, thereby commencing a new phase of both the joint venture between Interneuron and Wyeth Defendants and their combined relationship with Servier.

49. Interneuron had advised the FDA that withdrawal of the NDA from a financial standpoint was out of the question because the company would be ruined and, further, asked that continuing consideration and courtesies be extended Interneuron in its Redux application.

50. By October of 1994, Interneuron and Wyeth Defendants learned that there were many problems concerning the FDA's approval of Redux including that: (a) that secondary pulmonary hypertension was an adverse effect in patients treated with Redux; and (b) that the risk/benefit ratio of Redux was "unsatisfactory". Further, the FDA had indicated it had found Redux "unapprovable." However, at the request of Interneuron, the FDA agreed to withhold sending an unapprovable letter until April of 1995.

51. On or about January 5, 1995, Wyeth Defendants received further information on VHD among Pondimin users in the form of follow-up reports to those originally reported in 1994 as well as 6 new reports of VHD among Pondimin users. In the months of January, February, July and August of 1995 and thereafter, Wyeth Defendants received additional new reports of Diet Drug induced VHD, however, Wyeth Defendants failed to obtain any more information about these reports from any source; made no attempt to have the reports evaluated by any cardiologists; failed to undertake further testing or analysis of any sort; and made no attempt to look back through its computer database to look for other reports of VHD. Furthermore, Wyeth Defendants mislabeled VHD adverse events as "non-serious" and did not report many of these VHD adverse events to the FDA and refused to undertake any measures to ensure its Pondimin label included VHD as a possible adverse event.

52. On or about February 17, 1995, the FDA's Dr. Bilstad advised Interneuron's Dr. Sandage that the Redux NDA was nonapprovable and that the principal reason was because "the application did not contain adequate safety data to define the risk of developing pulmonary hypertension."

53. On June 15, 1995, the Wyeth Defendants' James Ottinger reported to Joseph Bathish the status of the European Committee on Proprietary Medicinal Product's ("CPMP") pharmacovigilance discussion wherein the CPMP working party concluded that a causal relationship between anorectic agents, like fenfluramine and dexfenfluramine, and the occurrence of pulmonary hypertension had been established.

54. On or about July 19, 1995, Interneuron, in its bid to have Redux approved, concluded that significant public relations and lobbying were needed as stated by Interneuron's Dr. Sandage: "[w]e agree that a significant PR/lobbying is needed. We will be getting numerous parties involved immediately. This includes the Washington, D.C. PR firm of Hill and Knowlton, possibly former US Surgeon General C. Everett Kroop, M.D., Nancy Taylor, and Yur Strobos, M.D., Ph.D. (for high level contacts at the FDA and Congress) Judy Stern, Ph.D. and Dick Atkinson (for working through American Obesity Association). We intend to add additional groups as necessary."

55. By 1995, additional medical reports and studies had been published further elevating the pre-existing scientific knowledge within the medical community that increases in serotonin caused VHD. These reports and studies, including Robolio PA, Rigolin VH, Wilson JS, et al. Carcinoid heart disease: correlation of high serotonin levels with valvular abnormalities detected by cardiac catheterization and echocardiography. Circ 1995;92:790-5, published on or about August 15, 1995 set forth a clear warning to all within the medical community including Defendants that serotonin releasing agents such as fenfluramine and dexfenfluramine cause VHD.

56. In September of 1995, JoAnn Manson, along with several of her colleagues at the Harvard Medical School, issued a press release regarding the results of a "study" of the health risks associated with obesity claiming that the data the authors had collected from the Nurses Health

Study provided compelling evidence for the proposition that "even mild to moderate overweight is associated with a substantial increase of premature death." In October of 1995, Dr. Manson testified before the FDA that this study supported the conclusion that the FDA should approve dexfenfluramine, though it later became evident that this fatally flawed and erroneous "study" found no statistically significant increased risk of mortality associated with mild to moderate obesity. Dr. Manson later revealed that she in fact was a paid consultant to Interneuron.

57. On or about September 15, 1995, Interneuron decided that it would secure the services of General Alexander M. Haig, Jr. to attend upcoming FDA meetings on Redux in an effort to exert pressure and influence aimed at the approval of Redux. Alexander Haig was hired by Interneuron and became Interneuron's Director.

58. In or about October, 1995, during the time Interneuron was continuing discussions with the FDA, Interneuron also attempted to secure the services of Newt Gingrich to exert influence upon the FDA.

59. On or about October 2, 1995, Dr. Rich advised Interneuron it was clear that evidence of safety for long-term use was lacking with respect to pulmonary hypertension. Dr. Rich advised Interneuron regarding the IPPHS data which showed the risk of significant injury being at least one in 10,000 users or 100 cases per million per year and questioned Interneuron as to the clinical safety of Redux based on Interneuron's own claims that Redux would cause weight reductions between 5% and 15%, which would translate into 248 lives saved per million per year. Further, Dr. Rich questioned the efficacy of Redux assuming Redux produced a consistent average 5% reduction in body weight stating, "[a]s I compute the 5% weight loss in a 300lb individual to a new weight of 285lbs, I question as to whether that will truly translate in substantial improvement in health to the patient." Dr. Rich further advised that the Redux label needed to clearly indicate to the prescribing physician that there is a causal relationship between Redux and the development of PH. However, the Integrated Summary of Safety for Redux as set forth in it label, without a Black Box Warning, ultimately stated that:

60. Anecdotal cases of PH have been associated with other weight loss agents such as phentermine and the racemic d,l-fenfluramine. In Europe, in post-marketing surveillance between 8/84 and 7/93 there were reports of PH in 51 patients being treated with dexfenfluramine

61. On or about October 12, 1995, Interneuron had further discussions with the FDA's Dr. Lutwak who confirmed the FDA's continued concerns about the safety of Redux which had proven to have resulted already in too many adverse event reports.

62. In or about November of 1995, Interneuron again attempted to push its lobbying efforts and caused to be issued a letter to Speaker Newt Gingrich stating: "This letter voices my deep concern about certain actions of the FDA. Our friends at the FDA are doing it again - I have used Pondimin for 22 years as a safe alternative to more stimulating drugs for obesity. I have never had any problems with it. An improved form, dexfen, has the same effect but without the drowsiness of the parent compound. It has been in general use since 1985 in Europe. The FDA has again denied our citizens an effective treatment of a potentially fatal disease (obesity)."

63. At a meeting of an FDA advisory committee on Redux, Interneuron solicited the services of Director Alexander Haig, who on behalf of Interneuron provided incorrect and unsubstantiated information to the FDA including representations that Redux helps twice as many people lose 10 percent of their weight as a placebo in preliminary tests and that ten million people have used the drug internationally without side effects.

64. On or about November 21, 1995, Defendant, Interneuron, entered into an exclusive "Contract Manufacturing Agreement" with Defendant, Boehringer, by which Boehringer agreed to manufacture, develop, test, assemble, package, label, prepare and/or supply Redux exclusively for and/or to Defendant, Interneuron, including supplying Defendant, Interneuron, with all of its requirements of Redux for ultimate sale in the United States including the State of Massachusetts, and the states where Plaintiffs ingested the Diet Drugs.

65. On or about January 18, 1996, the FDA advised Interneuron's Dr. Sandage that further changes to the labeling for Redux were recommended pursuant to the review of Dr. Lutwak

despite the fact that the FDA Advisory Committee had voted at a second meeting to approve Redux, albeit without the benefit of the safety information which Interneuron and the Wyeth Defendants had in their possession.

66. On or about April 29, 1996, the FDA approved Redux for sale in the United States and the first sales of Redux on the market in the United States began in June of 1996.

67. On or about July 17, 1996, after approval of Redux by the FDA, the FDA's Randy Hedin contacted Interneuron's Sonja Loar and reiterated again the FDA's ongoing concerns regarding pulmonary hypertension and the FDA's consideration of a Black Box Warning to which Interneuron voiced opposition in favor of continuing with the proposed bold-face, all CAPS warning.

68. On or about August 19, 1996 the FDA met with Interneuron and stated that it still felt a Black Box Warning may be appropriate for Redux, a fact that Interneuron later acknowledged given the serious and high risk of pulmonary hypertension associated with Redux.

69. On or about, August 26, 1996, the New England Journal of Medicine reported the final results of IPPH Study which had been preliminarily released in February 1994. The IPPH Study concluded that fenfluramine-based anorexigens, such as fenfluramine and dexfenfluramine, increased the risk of PH.

70. On or about August 29, 1996, an article was published in the New England Journal of Medicine authored by Dr. Stuart Rich and other preeminent doctors entitled Appetite-suppressant Drug and the Risk of Primary Pulmonary Hypertension" which addressed the results of the IPPH study and concluded that that the use of fenfluramine/dexfenfluramine substantially increased the risk of pulmonary hypertension in that the risk associated with dexfenfluramine use was equal to 14 deaths caused by per million patients treated thereby yielding a very "problematic" benefit:risk ratio of 20:1 or 280 lives saved for 14 deaths caused.

71. Defendants were aware of the result of the IPPH study by at least November 1995, well in advance of its official publication in the New England Journal of Medicine, nevertheless,

Defendants failed to apprise the public or physicians that the risk of contracting PH was many multiples of that previously reported by the Wyeth Defendants in their label and other literature. Even after the Brenot article and the preliminary release of the IPPH Study, Interneuron and the Wyeth Defendants failed to withdraw the New Drug Application ("NDA") for Redux and the Wyeth Defendants failed to remove Pondimin from the market when Interneuron and Wyeth Defendants knew of the extreme danger, causal relationship and substantial risk of harm associated with the use the Diet Drugs.

72. Even prior to their knowledge of the IPPH Study, the manufacturers and distributors of the Diet Drugs knew about the risks of PH associated with using the subject drugs from experience with and subsequent banning of such drugs in various countries in Europe as described herein above. Defendants did not apprise Plaintiffs, the public at large, or Plaintiffs' physicians of these material facts and risks.

73. Between 1994 and 1996, while fenfluramine was on the United States market and while dexfenfluramine was under FDA consideration, at least 30 cases of heart valve problems were identified among users of the Diet Drugs examined by physicians in Belgium. This information was reported to Belgian drug regulators and Servier. Servier's partners and or licensees, including Interneuron and the Wyeth Defendants, knew or should have known of the numerous reports of VHD among Diet Drug users.

74. Interneuron and Wyeth Defendants failed to properly investigate the reports and failed to warn doctors and consumers, including Plaintiffs, regarding the known risks of VHD associated with use of the Diet Drugs. Interneuron and Wyeth Defendants also did not adequately inform the FDA regarding the Belgian studies by suggesting that the reports were irrelevant because some of the studied individuals had also ingested herbs which Interneuron and Wyeth Defendants allegedly assumed caused VHD. In fact, Wyeth Defendants and Interneuron only reported one Belgian case to the FDA involving Redux's ingredient dexfenfluramine in an amendment to its Redux NDA.

75. During the time fenfluramine was sold on the United States market and at the time Interneuron filed its New Drug Application with the FDA for dexfenfluramine, Defendants had available to it the information that its European counterpart sub-licensee Servier had accumulated during its marketing of dexfenfluramine in Europe for over a decade concerning the safety and efficacy of the dexfenfluramine, including medical literature, adverse event reports relating to the use of the dexfenfluramine in Europe, clinical and other medical studies, and communications from medical providers. This information which was known or should have been known by Interneuron and Wyeth Defendants established inter alia, that:

a. by 1977, Defendants knew or should have known that the mechanism of action of the Diet Drugs and their affects on serotonin were responsible for causing pulmonary hypertension in exposed patients, and knew or should have known that the same mechanism of action also was likely the same mechanism which caused heart valve disease in carcinoid patients;

b. by 1992, Defendants knew or should have known that the Diet Drugs had been associated with fibrotic changes in the heart tissues of animals exposed to the drug;

c. by February of 1994, Belgian physician Mariane Ewalenko, MD advised Servier of seven patients who had been taking the Diet Drugs and who were found suffering from valvulopathy;

d. between 1994 and 1996, other Belgian physicians, including Jean Malak, MD and Jean-Francois Adam, MD, discussed and corresponded extensively with Servier officials regarding numerous cases involving valvular regurgitation suffered by patients who had ingested the Diet Drugs;

e. between 1994 and 1996, various Belgian doctors reported at least 30 cases of VHD associated with the use of the Diet Drugs;

f. between 1994 and 1996, numerous adverse event reports were received by Interneuron and Wyeth Defendants which provided or should have provided notice of the association between ingestion of the Diet Drugs and VHD; and

g. by 1995, available and reliable medical literature was available to Defendants from which Defendants' either knew or should have known that Diet Drugs caused an increase in circulating serotonin and that this very serotonin-related mechanism, also found in ergotamine toxicity and carcinoid syndrome, created a high risk for VHD.

76. On April 2, 1996, just three weeks before Redux was approved for marketing in the United States, Dr. B. Taylor Thompson, of Massachusetts General Hospital and Harvard Medical School provided an analysis of 32 pulmonary hypertension cases, which were part of the November 1995 Safety Update, to the FDA and to Interneuron and Wyeth Defendants. The Thompson analysis concluded that of the 32 cases, sixteen (16) cases involved secondary pulmonary hypertension. Dr. Thompson specifically placed Interneuron and Wyeth Defendants on notice that VHD was one of the primary causes for the secondary hypertension. Interneuron and Wyeth Defendants did not update the November 1995 Safety Update, which would have put the public, the FDA, and plaintiffs' physicians on notice of the relationship between Diet Drugs and VHD.

77. On April 29, 1996, the Defendants introduced the defective product Redux into the United States without informing the public, or Plaintiffs' physicians of the dangers and risks of VHD and secondary pulmonary hypertension associated with the Diet Drugs.

78. On or about June 1, 1996, Interneuron entered into a "Co-promotion Agreement" with the Wyeth Defendants which both reaffirmed the joint venture or partnership between Interneuron and the Wyeth Defendants and provided for Interneuron to market, promote, advertise, distribute, label, detail, supply, package and/or sell Redux in consideration for the payments from Interneuron's co-promoter, Wyeth Defendants, for percentages of profit derived from sales generated by Interneuron's sales representative sales force.

79. On or about August 28, 1996, only four months after approval of Redux, Interneuron and Wyeth Defendants were provided and reviewed a study entitled "Cardiac Adverse Effects of Fenfluramine Isomers" prepared by Dr. Francis Wagniart of Servier revealing a higher incidence among Redux users of PH than was previously known. The findings further established Interneuron

and Wyeth Defendants' knowledge of serious adverse side effects caused by the ingestion of the Diet Drugs. However, Interneuron and Wyeth Defendants failed to act responsibly in taking necessary action to protect the public, including Plaintiffs, from Diet Drug related injuries.

80. In March 1997, the Defendants were informed by doctors of heart valve problems among users of the Diet Drugs when they received a detailed report from physicians in meetings at the Mayo Clinic in Rochester, Minnesota. However, Defendants failed to undertake any action to warn or otherwise prevent further injury to the consuming public including Plaintiffs.

81. In July of 1997, the Mayo Clinic discovered additional cases of damage to heart valves caused by the Diet Drugs and made this additional information known to Defendants.

82. On or about July 8, 1997, the Mayo Clinic in Rochester, Minnesota released an emergency report linking the use of the Diet Drugs to unusual, potentially life-threatening disease related to heart valves.

83. Independent medical center data from the Mayo Clinic and elsewhere indicated that the Diet Drugs were associated with heart valve defects in as many as one-third of the patients who used the drug. The Mayo Clinic study concluded that dexfenfluramine users needed to be informed about the risk of PH and VHD.

84. Notwithstanding the fact that Interneuron and the Wyeth Defendants received detailed reports during separate meetings with investigators from the Mayo Clinic and the MeritCare Medical Center in Fargo, North Dakota regarding these findings as early as March of 1997, four months before the New England Journal of Medicine article reporting these findings was published, Interneuron and the Wyeth Defendants did not halt the wide spread use of the Diet Drugs until September of 1997.

85. On July 8, 1997, the FDA issued a public health advisory regarding the use of the Diet Drugs which stopped the implementation of the DEA's administrative action relating to de-scheduling.

86. On or about September 15, 1997, the FDA forced Defendants to withdraw the Diet Drugs from the United States market because the independent medical center data from the Mayo Clinic in Rochester, Minnesota, and elsewhere indicated that the Diet Drugs were associated with heart valve defects in as many as one-third of the patients who took the Diet Drugs alone or in combination with phentermine ("the initial Mayo study"). In fact, of 291 patients tested, one-third of them had damaged aortic or mitral heart valves; less than 1 percent of the general population has such damage.

87. On November 11, 1997, results of a study funded by the National Institute of Health ("NIH"), of the association between heart valve abnormalities and the use of the Diet Drugs, individually or in combination with phentermine, were reported at the annual conference of the North America Association for the Study of Obesity in Cancun, Mexico. The study, conducted by investigators at the Hennepin County Medical Center in Minneapolis, Minnesota ("the Hennepin study"), found significant heart valve leaks in 24% of 226 individuals taking one or more of these drugs.

88. Notably, the Hennepin study included a control or comparison group of 81 people matched by age, sex, height, and weight to the 226 cases. The 226 cases took fenfluramine and/or dexfenfluramine, while the 81 controls did not. Only 1% of the controls had significant heart valve leaks. All 307 individuals in the Hennepin study (cases and controls) had echocardiograms, which were read by physicians who were "blind" as to the status of each individual, i.e., the reading physicians had no knowledge as to whether the person had taken the diet drugs or not. The Hennepin study investigators found that dexfenfluramine ("Redux") is as likely to lead to heart valve defects as fenfluramine. Of the 226 patients observed in the Hennepin study, 145 had taken the combination of fenfluramine and phentermine, 40 had taken dexfenfluramine, 27 had taken dexfenfluramine in combination with phentermine, and 14 had taken all three drugs.

89. On November 13, 1997, officials from the FDA, NIH and the Centers for Disease Control issued a joint recommendation for medical monitoring of users of the Diet Drugs.

General Allegations

90. At all times material hereto, Defendants researched, created, formulated, tested, developed, designed, licensed, assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged and/or sold pharmaceutical Diet Drugs which were defective and unreasonably dangerous to consumers, including Plaintiffs.

91. Defendants knew or should have known that the Diet Drugs, when used alone or in combination with phentermine, created significant risks of serious injuries or disorders, including VHD, secondary pulmonary hypertension, related cardiopulmonary dysfunction, cardiomyopathy, congestive heart failure, and/or death, as to which Defendants failed to make proper, reasonable or adequate warning to the public about the risks associated with the use of their products.

92. At all times material hereto, though Defendants knew or should have known that dangerous risks were associated with the use of the Diet Drugs, Defendants proceeded to or permitted the Diet Drugs to be assembled, compounded, manufactured, marketed, promoted, advertised, distributed, labeled, detailed, supplied, packaged and/or sold without adequate warnings of the serious side effects and dangerous risks.

93. Both during the initial submission of the Redux NDA and thereafter, Interneuron and the Wyeth Defendants did not adequately report to the FDA, the public, and Plaintiffs' physicians information in its possession which related directly the risk of developing valvular heart valve disease and pulmonary hypertension. The public, the FDA, the medical community and Plaintiffs, were misled by these actions and omissions, resulting in Plaintiffs having received no or inadequate warnings regarding the true risks associated with ingesting Redux.

94. Interneuron and Wyeth Defendants failed to conduct sufficient and adequate pre-marketing research and testing to properly determine the risks and severity of serious side effects including VHD and/or pulmonary hypertension caused by the ingestion of Diet Drugs which Interneuron and Wyeth Defendants knew or should have known about.